

## **Remarks**

### ***Claim Amendments***

In this office action, claim 7 was amended and claims 17, 19-23 and 26-29 have been cancelled. After entry of this amendment, claims 7, 9, 18 and 25 will be pending in the application.

### **Support for the Amended Claims and Compliance with 35 U.S.C. § 132 and § 112**

#### **¶ 1**

The claims, as amended, recite “a purified antibody or fragment thereof which specifically binds an isolated FDF03-S1 polypeptide consisting of the amino acid sequence of SEQ ID NO: 6, wherein said antibody or fragment thereof is in complex with said FDF03-S1 polypeptide.” Support for this amendment can be found in claim 15 as originally filed. Claim 15 as originally filed recites a method for detecting an antigenic component by forming an antigen-antibody complex, including an antigen comprising the amino acid sequence of SEQ ID NO:6 and an antibody specific for SEQ ID NO:6.

The written description requirement of § 112 requires the application to convey with reasonable clarity to those skilled in the art that, as of the filing date, he or she was in possession of the invention. The claimed subject matter need not be described “*in haec verba*” in the original specification in order to satisfy the written description requirement. Rather, the test is whether a person of ordinary skill in the art would recognize that the applicant possessed what is claimed in the later filed application as of the filing date of the earlier filed application. The same standards govern whether new matter has been added to the specification.

Given the disclosure in originally filed claim 15, a person of skill in the art reading the application at the time it was filed would have understood that the inventors were in possession of “a purified antibody or fragment thereof which specifically binds an isolated FDF03-S1 polypeptide consisting of the amino acid sequence of SEQ ID NO: 6, wherein said antibody or fragment thereof is in complex with said FDF03-S1 polypeptide.” Therefore, the pending claims do not add new matter and satisfy the written description requirement.

### ***Rejection Under 35 U.S.C. § 112 - Enablement***

Claims 20-23 and 26-29 were rejected under U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. These claims have been canceled. Therefore, this rejection has been rendered moot.

### ***Rejections Under 35 U.S.C. § 112 – Written Description***

Claims 7, 9, 17-23 and 25-29 were rejected under U.S.C. § 112, first paragraph, as failing to comply with the written description requirement due to the recitation of the language “but does not bind a polypeptide consisting of the amino acid sequence of SEQ ID NO:2”. Since the rejected language has been canceled, this rejection has been rendered moot.

### ***Rejections Over the Prior Art***

#### ***The Pending Claims Are Novel over Lal (US Publication 2005/0155089)***

The claims are rejected under 35 U.S.C. § 102(e) as being anticipated by Lal. Applicants traverse.

Lal discloses the sequences of 184 proteins which contain a signal-peptide including a protein comprising the amino acid sequence of SEQ ID NO:6, but does not disclose any specific and substantial utility for any of these polypeptides. Therefore, as submitted in our reply to the previous office action, Lal does not enable a person of skill in the art to use the claimed invention and should not be prior art under 35 U.S.C. § 102(e). For the reasons of record, Applicants continue to submit that Lal is not a proper § 102(e) reference.

### ***Rejections Under 35 U.S.C. § 103***

The claims are also rejected as obvious over Lal in view of Markussen. Applicants traverse.

As discussed above, Lal is not a proper prior art reference under § 102(e). Thus, it cannot be used as a basis for an obviousness rejection.

In view of the arguments presented above, Applicants respectfully submit that the claims are novel and non-obvious over Lal.

***The Pending Claims Are Novel over Adema (WO 98/24906)***

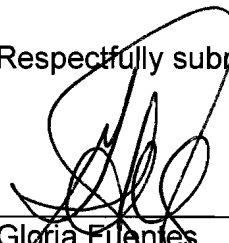
Adema discloses and claims the protein FDF03, having the amino acid sequence of SEQ ID NO:2. Adema does not disclose the protein FDF03-S1, having the amino acid sequence of SEQ ID NO:6. The pending claims are directed to "a purified antibody or fragment thereof which specifically binds an isolated FDF03-S1 polypeptide consisting of the amino acid sequence of SEQ ID NO: 6, wherein said antibody or fragment thereof is in complex with said FDF03-S1 polypeptide." Therefore, the claims are novel and non-obvious over Adema.

***Conclusion***

Applicants respectfully submit that the instant application is in condition for allowance.

Schering-Plough Corporation  
2000 Galloping Hill Road  
K-6-1-1990  
Kenilworth, New Jersey 07033-0530  
Tel: (908) 298-2266  
Fax: (908) 298-5388

Respectfully submitted,



---

Gloria Fuentes  
Attorney for Applicants  
Reg. No. 47,580